

**CENTER FOR DRUG EVALUATION AND
RESEARCH
74-890**

APPLICATION NUMBER:

CHEMISTRY REVIEW(S)

1. CHEMIST'S REVIEW NO.5

2. ANDA # 74-890

3. NAME AND ADDRESS OF APPLICANT

Applicant: TorPharm Inc.
50 Steinway Blvd.
Etobicoke, Ontario
Canada M9W 6Y3

U.S. Agent: Apotex USA, Inc.
Attention: Marcy MacDonald
1641 Barclay Blvd.
Buffalo Grove, IL 60089-4544

4. LEGAL BASIS FOR SUBMISSION

A basis for ANDA submission is included on page 004. Patent certification and exclusivity statements are included on pages 006-007.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

Tagamet

7. NONPROPRIETARY NAME

Cimetidine Tablets, USP

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Original Submission	April 19, 1996
Acknowledgment letter	May 14, 1996
New Correspondence	May 13, 1996
FDA Deficiency Letter	September 27, 1996
Amendment Response	March 7, 1997
New Correspondence	April 10, 1997
FDA Deficiency Letter	June 6, 1997
Amendment Response	September 26, 1997
FDA Fax Deficiency	March 10, 1998
Amendment Rspnse	March 20, 1998
FDA Minor Deficiency	July 14, 1998
Amendment Response	September 17 1998

10. PHARMACOLOGICAL CATEGORY

Antiulcer

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

NDA #17-920
DMFs

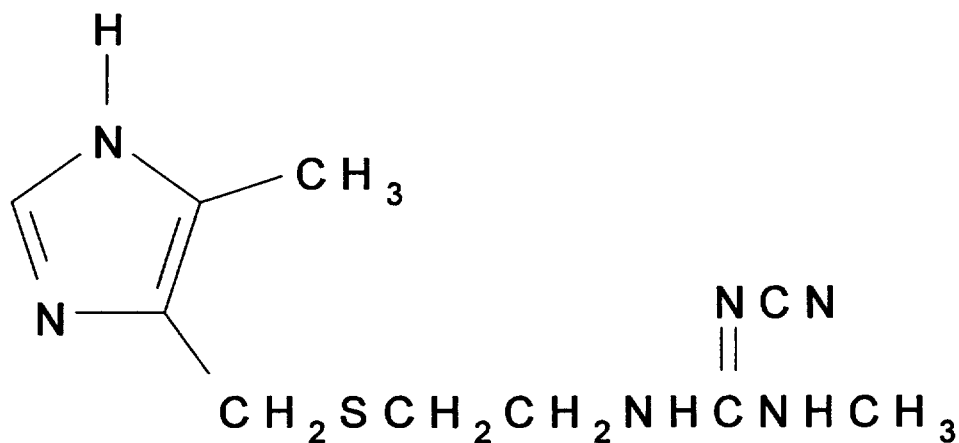
13. DOSAGE FORM
Tablet

14. POTENCY
200, 300, 400, and 800 mg

15. CHEMICAL NAME AND STRUCTURE

N"-cyano N-methyl -N'-(2-((5-methyl-1 H imidazole-4-yl)methyl)thio-ethyl)-guanidine

Cimetidine USP
 $C_{10}H_{16}N_6S$; M.W. = 252.34



2-Cyano-1-methyl-3-[2-[[(5-methylimidazol-4-yl)methyl]thio]-ethyl]guanidine. CAS [51481-61-9]

16. RECORDS AND REPORTS
N/A

17. COMMENTS

All deficiencies have been resolved satisfactorily.

18. CONCLUSIONS AND RECOMMENDATIONS

This application can now be approved.

19. REVIEWER:

Karen A. Bernard, Ph.D.

DATE COMPLETED:

10/5/98

Page(s) 19

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chem Rev 5
10/5/98